Remarks

Claim Amendments

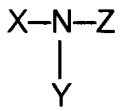
Claims 1-6 are currently pending and stand rejected. By way of the foregoing amendments, claims 1 and 5 are amended.

§102/103 Claim Rejections Cole-Watson-Shapiro

The Examiner maintains the rejection of claims 1-6 as being anticipated by, or alternatively obvious over, each of U.S. Patent No. 6,444,195 to Cole ("Cole"), U.S. Patent No. 6,482,446 to Watson ("Watson") and U.S. Patent No. 6,372,791 to Shapiro ("Shapiro"), alone. In upholding the rejection, the Examiner states that Applicant's arguments are not critical as the instant claims are "not particularly drawn to a method of treating acne using only active agent **consisting of** a mixture of alkanolamines, lipoic acid and tyrosine." (October 7, 2005 Office Action, p.4, emphasis added.) Applicant respectfully asserts that the claims as amended herein, do recite such elements.

Specifically, as amended, all claims of Applicant's present invention are directed to a topical acne composition **consisting of:**

a) **from about 0.1% to about 10% by weight of an alkanolamine** of the formula:



wherein X, Y and Z are selected from the group consisting of hydrogen, C_1-C_3 alkyl groups, C_2-C_4 alkanol group, wherein at least one of X, Y, or Z is a C_2-C_4 alkanol group bearing at least one hydroxyl group and optionally at least one carboxyl group;

b) **from about 0.01% to about 6% by weight tyrosine**;

c) **from about 0.01% to about 10% by weight of a sulfur-containing ingredient** selected from the group consisting of lipoic acid, glutathione, and mixtures thereof, and

d) a dermatologically acceptable carrier, **wherein the topical composition is applied to skin and acts to treat or prevent acne**. (*See* Applicant's claim 1, amended herein.)

Applicant respectfully disagrees that the neither of these references, alone or in combination, discloses or suggests all elements of at least Applicant's independent claim 1, namely a composition consisting of the key active ingredients of from about 0.1% to about 10% by weight of an alkanolamine of the recited formula; from about 0.01% to about 6% by weight tyrosine; and from about 0.01% to about 10% by weight of a sulfur-containing ingredient, in a dermatologically acceptable carrier, wherein the topical composition is applied to skin and acts upon the skin to treat or prevent acne. (*See* Applicant's claim 1, amended herein.) Applicant addresses each reference individually below.

Cole

The Examiner has cited Cole for teaching acne-treating agents comprising alkanolamine, lipoic acid, and tyrosine, (Applicant's claim 1 elements) as well as and hydroxyl acids, and ascorbic acid derivatives (claims 4-5) and has asserted that Cole discloses these agents in amounts of .001-20%. Applicant respectfully disagrees.

Cole is directed to sunscreens containing dibenzoylmethane derivative, one of the most commonly used UV-A absorbers (to block UV-A radiation from reaching the skin, preventing sunburn, wrinkles, skin cancer and other sun damage to skin). (Cole at col. 1, lines 10-15, 20-23) In a direct attempt of solving the problem of photochemical instability of dibenzoylmethane derivatives, the inventors of Cole discovered that the

specific combination of dibenzoylmethane derivative and di/polyester of naphthalene dicarboxylic acid increases the photo-instability of dibenzoylmethane. (*Id.* at col. 1, line 65 to col. 2, line 4.) Hence, one of skill in the art would understand from Cole that its compositions have the purpose of creating effective sunscreens, and do not disclose or suggest compositions effective to act upon the skin to treat or prevent acne, as recited by the present claims. (*See* amended claim 1.)

It is in the laundry list of potential adjunct ingredients to the dibenzoylmethane and di/polyester of naphthalene sunscreen formulation where the Examiner hunts for ingredients using hindsight gained from the disclosure of Applicant's invention. Such hindsight analysis is improper. Further, in fact, these adjunct ingredients are included in Cole merely for good measure as generally-accepted additives, and *not* to achieve any particular goal other than for what already is known by one of skill in the art based on their inherent properties, i.e. "to enhance the therapeutic effectiveness," as explicitly confirmed by the Examiner . (Cole col. 4, line 66 to col. 5, line 45; October 7, 2005 Office Action at p. 5.) Adjunct ingredients listed are vitamins, botanical extracts, antimicrobial agents, anti-inflammatory agents, skin smoothing agents, and antifungal agents, to name a few. (*Id.*) There-within, alkanolamines (col. 5 lines 5), tyrosine, included as one potential example of the adjunct ingredient of an amino acid (col. 5, line 15); and lipoic acid (col. 5, line 14) are mentioned. At best, this disclosure in Cole merely suggests that any of the thousands of imaginable combinations that could be made from the laundry list of adjunct ingredients (only one of which theoretically could include these three components of the present claims), enhances the therapeutic effectiveness of its sunscreen formulation. However, Cole does not teach or suggest to one of skill in the art to pick these three specific ingredients from the laundry list and combine them in a dermatologically acceptable carrier to arrive at a composition to apply to skin to act upon the skin to treat or prevent acne. (Amended claim 1.) Nor does Cole's general disclosure of these thousands of possible combinations of adjunct ingredients amounting in total to 0.1-20% by weight of the final composition (Cole at col.

3, line 35) teach or suggest one of skill in the art to pick specifically from about 0.1% to about 10% by weight of an alkanolamine of the recited formula; from about 0.01% to about 6% by weight tyrosine; and from about 0.01% to about 10% by weight of a sulfur-containing ingredient, in a dermatologically acceptable carrier, wherein the topical composition is applied to skin and acts upon the skin to treat or prevent acne. (Amended claim 1.)

While the required ingredients of Applicant's claim 1 can be found buried amidst a large amount and variety of other ingredients provided generally in a laundry list, such mention-in-passing of each of these ingredients individually does not amount to a disclosure, nor a suggestion, of the *specific combination* of those three key ingredients, and the beneficial, surprising effects with respect to acne that the combination achieves in Applicant's present invention. A general disclosure of percentage by weight of one or more of ingredients on a laundry list does not amount to a disclosure or a suggestion of the *precise ranges of each of the key active ingredients* recited in Applicant's claim 1. There is no teaching in Cole of which few, within the laundry list of the several, ingredients to combine and which to not include (nevermind in what percentages by weight of each) to arrive at Applicant's invention, nor is there motivation to look to teachings regarding *adjunct* ingredients in a sunscreen whose primary active ingredient serves as a chemical that blocks UV-A radiation to prevent it from reaching the skin (and preventing deleterious effects – wrinkles, burn, cancer – from ever occurring), rather than *acting directly upon* the skin, to find ingredients to be employed in a specific combination to act upon the skin. Further, there is no motivation to look to the teachings of adjunct ingredients that merely "enhance the therapeutic effectiveness" of a composition whose main ingredient does *not* act upon the cells of the skin, in order to find a specific combination of adjunct ingredients, each in specific weight percentage ranges, that must act directly upon the cells skin in topical *acne* composition to *treat* an existing skin disease of *acne*, and/or prevent further *acne* from forming. Hence, for at

least these reasons, Cole fails to teach or suggest Applicant's claims, overcoming the Examiner's rejection.

Watson

Watson is directed to astringent composition having a relatively low alcohol concentration and increased viscosity values, containing astringent plus alcohol, and method of use, designed to overcome the problems of consistency and resulting difficulty in use and application of astringents. (Watson col. 1, lines 32-34; col. 2, lines 14-30.) The astringents may further include adjunct ingredients that do not serve to address the problems the invention seeks to relieve. (*Id.* at col. 2, line 61 to col. 3, line 67.) These adjunct ingredients are included merely for good measure as generally-accepted additives, and *not* to achieve any particular goal other than for what already is known by one of skill in the art based on their inherent properties. Adjunct ingredients listed are sunscreen agents, botanical extracts, antimicrobial agents, anti-inflammatory agents, skin smoothing and soothing agents, and antifungal agents, to name a few. (*Id.*) Within the laundry list of adjunct ingredients, 2-dimethylaminoethanol (col. 3 lines 4), tyrosine (included as one potential example of the adjunct ingredient of an amino acid) (col. 3, line 5), and lipoic acid (col. 3, line 5) are mentioned. Just as in the disclosure in Cole, Watson generally states that any of these one or any combination of the several adjunct ingredients (in total) amount to 0.1-20% by weight of the final composition. (*Id.* at col. 3, line 11.)

Such mention-in-passing of each of these ingredients individually does not amount to a disclosure, nor a suggestion, to make a *specific combination* of those three ingredients to treat or prevent acne, and the beneficial, surprising effects of that the composition consisting of these ingredients in specific combination, in a dermatogolically acceptable carrier, as required by the present claims. (Amended claim 1.) A general disclosure of percentage by weight of one or more of ingredients on a long list does not amount to a disclosure or a suggestion of the *precise ranges of each of the three key active ingredients* as recited in Applicant's amended claim 1. There is no teaching of which

few, within the laundry list of the several, ingredients to combine and which to not include, to arrive at Applicant's invention, (nevermind in what exact percentages by weight of each) nor is there motivation to look to teachings regarding *adjunct* ingredients in an astringent whose primary active ingredients serve to bind and tighten soft tissue and tone skin to find ingredients to be employed in a specific combination to act upon the skin in a method of treating an existing skin disease, *acne,* and preventing further *acne* from forming.

Moreover, even if *arguendo*, there was a teaching of any of Applicant's ingredients, there would be motivation to combine teachings of an astringent and other alcohol-containing compositions as they are often too drying and harsh to be used on acne-affected skin and would not be referenced for insight in treatment of the skin disease of acne. (*See* Application at ¶ [0032], discussing alkanolamine compositions as advantageous in light of anti-inflammatory and anti-acne properties as conventional acne products, such as astringents cause redness and inflammation to sensitive skin). Hence, for at least these reasons, Watson patent fails to teach or suggest Applicant's claims, overcoming the Examiner's rejection.

Shapiro

Shapiro is directed to a method of promoting metabolism, energy production and uptake and utilization of oxygen in the skin, by applying a combination of i) carnitine, or salt or ester thereof, and ii) pyruvic acids or salt or ester thereof. (*See* Shapiro Abstract) Resultantly, skin firmness, elasticity, tone, texture and barrier function is said to be improved. (Shapiro at col. 1, lines 35-38.)

In contrast to the composition consisting of the three key active ingredients recited in Applicant's claim 1, Shapiro merely includes a laundry list of potential adjunct ingredients to its primary active ingredients of carnitine and pyruvic acid. (*Id.* at col. 4, lines 13-44.) These adjunct ingredients are included merely for good measure as generally-accepted additives, and *not* to achieve any particular goal other than for what

already is known by one of skill in the art based on their inherent properties. Adjunct ingredients listed are sunscreen agents, botanical extracts, antimicrobial agents, anti-inflammatory agents, skin lightening agents, and antifungal agents, to name a few. (*Id.*) Within this laundry list of adjunct ingredients, 2-dimethylaminoethanol (col. 4, line 24); tyrosine (col. 4, line 55), sulfur resorcinol (col. 4, line 21), and lipoic acid (col. 4, line 20) are mentioned in pasing. Exactly as Cole and Watson, Shapiro generally states that any of these one or more adjunct ingredients (in total) amount to 0.1-20% by weight of the final composition. (*Id.* at col. 4, lines 30-31.) While these ingredients of Applicant's claim 1 can be found buried amidst a large amount and variety of other adjunct ingredients provided generally in a laundry list, such mention-in-passing of each of these ingredients individually does not amount to a disclosure, nor a suggestion, of the *specific combination* of those three ingredients in a dermatologically acceptable carrier to treat or prevent acne and the beneficial, surprising affects of the topical composition consisting of these ingredients as achieved by Applicant's present invention. (*Id.*) A general disclosure of percentage by weight of one or more of ingredients on a long list does not amount to a disclosure or a suggestion of the *precise ranges of each of the key active ingredients* recited in Applicant's claim 1. There is no teaching of which few, within the laundry list of the several, ingredients to combine and which to not include (nevermind in what percentages by weight of each) to arrive at Applicant's invention. Nor is there motivation to look to teachings regarding adjunct ingredients in a composition having carnitine-pyruvic acid active ingredients to promote oxygen consumption by the skin in order to find key active ingredients to be employed in a composition consisting of alkanolamines, tyrosine, a sulfur composition, and a dermatologically acceptable carrier, for use in topical acne composition to treat the existing skin disease of *acne,* and prevent further *acne* from forming. Hence, for at least these reasons, Shapiro fails to teach or suggest Applicant's claims, overcoming the Examiner's rejection.

With respect to all of the above rejections, the Examiner states that even if the claimed composition is not be included within the examples, and *moreover*, even if the weight amounts of each are not individually taught, it would have been readily apparent to any skilled artisan how to make the composition comprising such ingredients with titrating effective dosage. (*See* Office Action, page 6.) Applicant respectfully disagrees. One of skill in the art could not from the teachings in the cited references and/or from his or her knowledge of the art, be able to pick out the three components from the thousands of possible combinations of adjunct ingredients, and know that they together these specific three would be the key ingredients of a topical composition wherein the composition is applied to skin and acts upon the skin to treat or prevent acne, as recited by the claims as presently amended. Further, neither of these references would suggest or teach one of skill in the art to provide each of the three key ingredients in their specific effective amount in ranges as recited in the present claims.

§102(e) Claim Rejection – Perricone patents

U.S. Patent No. 6,319,942 to Perricone

The Examiner has entered a rejection on the grounds of anticipation and/or obviousness under 35 U.S.C. §102(e) over U.S. Patent No. 6,319,942 ("Perricone'942").

Perricone'942 discloses a method for the treatment or inhibition of cutaneous scar tissue, which comprises topical application to the scars or injured skin areas of an effective amount of an alkanolamines, preferably about 1% to about 3% by weight of the total composition, in a carrier. (Perricone'942 Abstract; col. 3, lines 59-60.) Optional adjunct ingredients of lipoic acid, tyrosine, a fatty acid ester of ascorbic acid, and/or an alpha-hydroxy acid may be added to scar-reducing formulations of the invention. (*Id.* at col. 5, lines 27-30.)

While in hindsight, picking two specific optional adjunct ingredients of several listed in Perricone'942, guessing at their amounts, and adding them to its active ingredient of alkanolamines, one may arrive at the three required ingredients and their amounts of the present invention; however, the suggestion to make such a combination to arrive at the three key ingredients of the present claims, in the correct amounts, and in turn apply the composition to the skin to treat or prevent acne, is completely absent from the disclosure of Perricone'942. Hence, one of skill in the art would not understand the Perricone'942 method of scar treatment as teaching or suggesting a topical acne composition consisting of the key ingredients from about 0.1% to about 10% by weight of an alkanolamine of the recited formula; from about 0.01% to about 6% by weight tyrosine; from about 0.01% to about 10% by weight of a sulfur-containing ingredient; and a dermatologically acceptable carrier, wherein the topical composition is applied to skin and acts upon the skin to treat or prevent acne. (*See* Applicant's claim 1, amended herein.)

U.S. Patent No. 6,500,857 to Perricone

The Examiner has entered a rejection on the grounds of anticipation and/or obviousness under 35 U.S.C. §102(e) over U.S. Patent No. 6,500,857 ("Perricone '857") which is directed to a method for stimulating subcutaneous muscles by applying a composition containing at least one acetylcholine precursor and/or at least one compound exhibiting catecholamine activity to the overlying skin area, and then electronically stimulating the overlying skin area using electrical pulses. (Perricone '857 Abstract.) Optional adjunct ingredients such as alpha-hydroxy acids (e.g., glycolic acid), a fatty acid ester of ascorbic acid (e.g., ascorbyl palmitate), and/or lipoic acid are disclosed. (*Id.* at col. 2, lines 55-57.) Perricone '857 discloses these methods to increase muscle tone and in turn improve the appearance of tissues affected by aging. (*Id.* at col. 2, lines 39-41.)

While in hindsight, picking two specific of the several optional adjunct ingredients of Perricone'857, guessing at their amounts, and adding them to its active ingredient of an acetylcholine precursor, may lead one to arrive at the three required ingredients of the present invention, still the suggestion to make such a combination to arrive at the three key ingredients of the present claims, in the correct amounts, and in turn apply the composition to the skin to treat or prevent acne, is completely absent from the disclosure of Perricone '857. One of skill in the art would not understand the disclosed method for stimulating subcutaneous muscles in Perricone '857 as teaching or suggesting a topical acne composition consisting of the key ingredients from about 0.1% to about 10% by weight of an alkanolamine of the recited formula; from about 0.01% to about 6% by weight tyrosine; and from about 0.01% to about 10% by weight of a sulfur-containing ingredient, in a dermatologically acceptable carrier, wherein the topical composition is applied to skin and acts upon the skin to treat or prevent acne. (*See* Applicant's claim 1, amended herein.)

It is respectfully submitted that the 35 U.S.C. §102(e) anticipation and obviousness rejections over Perricone '942 and Perricone '857 are traversed because of the complete absence of disclosure of the specific combination of alkanolamines, tyrosine and a sulfur ingredient, and in the effective ranges recited, and that the rejections should be withdrawn.

Conclusion

Applicant respectfully asserts that the Examiner's rejections have been traversed by the aforementioned amendment and remarks. It is respectfully submitted that all of the pending claims are in order for allowance and early notice to that effect is respectfully requested.

Respectfully submitted,

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